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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/321,766	05/28/1999	AWADHESH K. MISHRA	28069-523	7018

7590 05/28/2009
MINTZ, LEVIN, COHN, FERRIS, GLOVSKY & POPEO, P.C.
CHRYSLER CENTER
666 THIRD AVENUE, 24TH FLOOR
NEW YORK, NY 10017

EXAMINER

FAY, ZOHREH A

ART UNIT	PAPER NUMBER
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1612

MAIL DATE	DELIVERY MODE
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05/28/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/321,766	Applicant(s) MISHRA, AWADHESH K.	
	Examiner ZOHREH A. FAY	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-38, 40-46, 48-54, 56, 57 and 63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-38, 40-46, 48-54, 56, 57 and 63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 7, 2009 has been entered.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 21-38, 40-46, 56, 57 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muller et al. (U.S. Patent 5,858,410) and Anderson et al. (5,739,152).

Muller et al. teach a nanosuspension comprising 0.001-30% lecithin (claims 1, 13, 15), the compounds, polyvinyl alcohol, ploxamer, glucose, mannose trehalose and sorbitol at 0.1-2% (claims 1-22) and 0.1-30% (claims 1, 7). Parental, intramuscular, and subcutaneous administration is disclosed (column 6, line 61, column 9, line 33).

Antimycotic, corticoid and immune therapeutics such as cyclosporine are specified (claims 39, 48). Autoclaving is disclosed (figures 13, 14). Anderson et al. teach autoclaving a dispersion of active agent under nitrogen to get a composition, which is stable. (Column 6, line 64- column 7, line 9). It would have been obvious to a person skilled in the art to improve the stability of the Muller et al. suspension by autoclaving under nitrogen in view of Anderson et al.

One skilled in the art would have been motivated to combine the teachings of the above references, since one relates to the use of the claimed active ingredients in combination with phospholipids, polyvinyl alcohol, polxamer, glucose, manose, trehalose and sorbital in a pharmaceutical formulation, which are autoclaved, and the other relates to autoclaving as a mean of stabilizing pharmaceutical formulations. The determination of optimum proportions or amounts is considered to be within the skill of

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the artisan. Applicant's amendment to change "containing" to "consisting essentially" has been noted and reviewed. There is no evidence of record to demonstrate that the addition of a surfactant would materially change the nature of the invention. Such phrase also does not overcome the obviousness rejection in terms of proportions or amounts in the absence of any support to the advantages of such proportions. Applicant's arguments and remarks have been carefully considered, but are not deemed to be persuasive. Applicant alleges criticality to the lack of surfactant of the claimed composition in comparison with the composition of prior art that contains a surfactant. The arguments are not well taken. Applicant has used the composition as used by the prior art without a surfactant, and has autoclaved such composition. The fact that applicant has discovered a composition of the prior art without the surfactant can be autoclaved and stay stable does not create a patentably distinct invention in the absence of evidence to the contrary. The prior art clearly teaches that the composition of the instant application with the addition of a surfactant, can be autoclaved and stay stable. The determination of optimum proportions or amounts are considered to be within the skill of the artisan. Applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention, and as such, the prior rejection sustains.

Applicant's arguments and declaration have been carefully considered. Applicant alleges criticality to the lack of surfactant of the instant application in comparison with the composition of the prior art having surfactants. Applicant in his remarks refers to example 13 in the Muller reference, and state that such example does

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not use a surfactant, but uses a viscosity enhancing agent, such as a cellulose derivative. Applicant is reminded that the claims of the instant application only exclude certain surfactants and not a viscosity enhancing agent. Therefore, the example 13 of Muller et al. reads on the claimed composition.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ZOHREH A. FAY whose telephone number is (571)272-0573. The examiner can normally be reached on Monday to Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ZF
/Zohreh A Fay/
Primary Examiner, Art Unit 1612

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